DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AMD Lasers, LLC
% Ms. Amy Szentes
7405 Westfield Boulevard
Indianapolis, Indiana 46240

SEP 16 2011

Re: K102359
Trade/Device Name: Picasso™/Picasso Lite™/Picasso Perio™
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: September 06, 2011
Received: September 09, 2011

Dear Ms. Szentes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

AMD LASERS
Effective. Practical. Affordable. World Class Lasers

Indications for Use

510(k) Number (if known): K102359

Device Name: PICASSO™/ PICASSO LITE™/ PICASSO PERIO™

Indications For Use:
The Picasso™/Picasso Lite™/ Picasso Perio™ is generally indicated for incision, excision, vaporization, ablation and coagulation of oral soft tissues including the following:

- Gingival troughing for crown impression
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis and coagulation
- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy and frenotomy
- Implant recovery
- Incision and drainage of abscess
- Leukoplakia
- Operculectomy
- Oral papillectomies
- Pulpotomy
- Pulpotomy as an adjunct to root canal therapy
- Reduction of gingival hypertrophy
- Soft tissue crown lengthening
- Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa
- Vestibuloplasty

Laser periodontal procedures, including:
- Sulcular debridement (curettage, removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including: gingival index, gingival bleeding index, probe depth, attachment loss, and tooth mobility).
- Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium.

Teeth Whitening Indications (Picasso Only):
- Laser assisted whitening/bleaching of teeth
- Light activation for bleaching materials for teeth whitening.

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New Indication for Use:
In addition to the aforementioned indications of use previously cleared by the FDA, the following indication is requested to be added:

Laser periodontal:
Picasso assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium).

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102359

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